State Fiscal Year 2002

Annual Report of the Department of Rehabilitative Services Human Research Review Committee

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Commissioner

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Authority and Duties of the Committee

Section 51.5-5.1 of the Code of Virginia requires the Department of Rehabilitative Services (DRS) Human Research Review Committee (HRRC) to submit to the Governor, the General Assembly, and the DRS Commissioner at least annually a report on the human research projects reviewed and approved by the Committee, including any significant deviations from proposals as approved. This report presents State Fiscal Year 2002 activities of the DRS HRRC.

The HRRC has internal oversight responsibilities for ensuring protection of the rights and welfare of DRS consumers who volunteer to participate in research conducted or authorized by the department or any of its partner organizations covered by the Code. The DRS Commissioner established the Committee in August 2000 to review and approve all research to be conducted or authorized by DRS or the Woodrow Wilson Rehabilitation Center (WWRC), as well as the Centers for Independent Living (CILs) and Virginia Employment Services Organizations (ESOs) that partner with DRS in the delivery of services to persons with disabilities. Elizabeth E. Smith, DRS Policy and Planning Director, is the Committee's Chair and this is the Committee's second annual report. The composition of the Committee is governed by 22 VAC 30-40-60 and a list of Committee members is provided at Appendix A.

The regulation gives DRS partner organizations the options to: 1) establish their own research review committee; 2) work with other institutions to establish a single committee; or 3) use the DRS established committee. Since the SFY 2001 annual report, three new ESOs have been added to the list of the organizations that partner with DRS to deliver employment services. All three new ESOs[1] designated the DRS HRRC as their human research review committee. As of this report, there are 103 organizations under the DRS umbrella (Woodrow Wilson Rehabilitation Center, one university based rehabilitation research and training center, 16 Centers for Independent Living, and 85 Employment Services Organizations[2]).

[1] The three ESOs that became DRS partners during SFY 2002 are: Commonwealth Supportive Services, Employability Counseling and Consulting, and PORTCO, Inc.
[2] The actual number of ESOs that have Federal Identification Numbers (FINs) is greater than the number of ESOs reported here because several ESOs have administrative authority for a network of other ESOs and speaks for all

To carry out its oversight responsibilities, the Committee reviews and approves applications for proposed research. The Committee follows regulatory procedures as specified by 22 VAC 30-40-10 et seq. and applicable Federal regulations concerning human subject research. The primary Federal regulatory body is the Department of Health and Human Services. To supplement regulatory requirements, the Committee has a procedures manual which standardizes Committee practices and activities, describes study participant complaint procedures, specifies the responsibilities of investigators, and provides templates for: 1) investigator application, 2) voluntary informed consent, and 3) investigator periodic progress reports.

The Committee meets monthly, or as needed, to fulfill its responsibilities and must meet at least once annually. A quorum of the Committee consists of a majority of its members including at least one member whose primary concerns are in nonscientific areas. The Committee's responsibilities begin when a research proposal is submitted to the Chair for Committee review and approval. Elements of the Committee's review include consideration of potential benefits and risks and the methodology of the research, the degree of risk for nontherapeutic research, the protection of the rights and welfare of participants, voluntary informed consent, competency of the research investigators, equitable selection criteria for research participants, whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants, and adherence to other criteria if established by the DRS Board of Rehabilitative Services. All research proposals are reviewed within 45 days of submission of a completed application. Research investigators are notified in writing of the Committee's decision to approve or disapprove the proposed research activity, or of modifications required to secure approval.

Overview of Reviewed and Approved Research

Ten studies were reviewed and six of these studies were approved by the HRRC during State Fiscal Year 2002. Two studies were approved by "exempt review", four studies were approved by "expedited review", two investigators withdrew their applications, one study did not meet the

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members of the network. As an example, Frontier Health is composed of several branches (Developmental Services, Independence Unlimited, Opportunities Unlimited-Bristol, and Opportunities Unlimited-Kingsport) and the same administrative authority covers all branches of Frontier Health.

definition for research, and one application was returned to the investigator without action because WWRC made the administrative decision to not participate in the study. The Committee has no evidence suggesting that there have been any significant deviations from these proposals as approved. A list of research proposals reviewed by the Committee is at Appendix B. The three types of review are explained at Appendix C.

The Committee received two continuing review applications for research proposals that were initially approved during SFY 2001 (see list at Appendix D) and conducted one site visit for one of the continuing review studies. The principle investigators for both studies were cited for deviations from the research protocols as initially approved by the Committee. One investigator added an additional consent form to the protocol (DRS Human Research Review Control # 00007) that had not been reviewed and approved by the Committee. The investigator was sent a written reminder that the Committee must review and approve all proposed changes to previously approved research prior to implementing changes. The Committee Chair and Vice Chair conducted a site visit for the other study that required continuing review (DRS Human Research Review Control # 00008). The site visit, conducted on June 25, 2002, identified significant deviations from the approved research protocol and the study was suspended pending receipt of appropriate documentation of the revised protocol and informed consent form and upon the Committee's review and approval.

Overview of DRS

DRS is committed to increasing high-quality employment outcomes for people with disabilities by providing effective services and by working with employment and training programs, service providers, and employers to achieve the employment and independence of people with disabilities. DRS administers the federal-state funded Vocational Rehabilitation (VR) program that provides individuals with disabilities with a comprehensive array of services to enable them to obtain, retain, or advance in employment. These services include vocational evaluation, job placement, career counseling, vocational and academic training, rehabilitation technology, physical restoration, and personal assistance service. DRS operates WWRC, which provides comprehensive services to people with physical, mental, sensory, and emotional disabilities.

WWRC consumers participate in residential or outpatient programs ranging from early medical rehabilitation to complete vocational services and re-entry to the community. In addition to its agency programs, the Department has strong partnerships with many community-based rehabilitation providers across the Commonwealth. For example, DRS purchases facility-based employment and supported employment services from ESOs, the Community Rehabilitation Providers in Virginia. Using a combination of federal and state dollars, DRS provides extended employment, situational assessment, supported employment, and work adjustment training through the ESOs. DRS also works closely with private, non-profit Centers for Independent Living (CILs), which provide independent living skills, training, advocacy, information and referral, and peer counseling for individuals with disabilities, as well as with community organizations and state agencies involved with education and training for people with disabilities.

Appendix A: Department of Rehabilitative Services Human Research Review Committee Members

Frederick Capps, Ed.D.
Director of Psychological Services
Woodrow Wilson Rehabilitation Center

Lynn Sewell
CES Manager
Chesterfield Employment Service

E. Davis Martin, Jr., Ed.D.
State Rehabilitation Council

Michael Nakatsuka
DRS Consumer

[4]Myra Owens, M.S.
Lead Analyst Research & Evaluation
Policy and Planning Division, DRS

Asha Rodwell, M.S., CRC
Vocational Rehabilitation Counselor, DRS

[3] Elizabeth Smith, J.D., M.S.
Director Policy and Planning, DRS

Terry Vaughn
Citizen, Commonwealth of Virginia

Sandra Wagener
Executive Director
Central Virginia Independent Living Center

Steven L. West, Ph.D.
Department of Rehabilitation Counseling
Virginia Commonwealth University

[3] Chair, HRRC

[4] Vice Chair, HRRC

Appendix B: Studies Reviewed During State Fiscal Year 2002

Study Title	Type of Review	Date approved	Periodic Review	DRS Control Number
Enhancing Consumer-Counselor Working Relationships in Rehabilitation: An Empirical Research Investigation of Counseling Expectancies and Working Alliances Variables for Optimizing Consumer-Counselor Relationships, Consumer Satisfaction, and Rehabilitation Outcome	NA	Investigator withdrew application		SFY02-00001
Evaluation of selected employment support organizations (ESO's) serving temporary assistance for needy family (TANF) clients in the Commonwealth of Virginia	Expedited	11/4/2001	Annual	SFY02-00002
Test-Retest Reliability of the Lin Interest Checklist on Individuals with Spinal Cord Injuries (SCI)	NA	Investigator withdrew application		SFY02-00003
A 12-week, multicenter, randomized, double-blind, placebo-controlled preliminary study to determine the efficacy and safety of Donepezil Hydrochloride (E2020) in patients with persistent mild to moderate impairments resulting from a single closed head injury	NA	WWRC elected not to participate in the study		SFY02-00004
An Investigation of Personal-Social Contextual Factors of the Online Adult Learner: Perceived Ability to Complete and Succeed in a Program of Study	Expedited	11/27/2001	Annual	SFY02-00005
An Empirical Investigation of the Effects of Leadership Development Training on the Visionary Leadership Characteristics and Behaviors of Emerging Leaders within Their Organizational Contexts	Expedited	1/22/2002	Annual	SFY02-00006
Evaluation of the Brain Injury Association of America's Partnership for Information and Communication Grant - Year 3	NA	Study was a program evaluation and did not meet the definition of research		SFY02-00007

Appendix B: Studies Reviewed During State Fiscal Year 2002 (Continuation)

Study Title	Type of Review	Date approved	Periodic Review	DRS Control Number
Similarities vs. Differences: Examining Counselor and Client Pairings as they Relate to Job Placement in Vocational Rehabilitation Settings	Expedited	4/2/2002	Annual	SFY02-00008
FY 2003 Public Input Survey	Exempt	3/20/2002	Annual	SFY02-00009
The Development and Validation of a Rehabilitation Planning and Outcome Measurement System	Exempt	4/22/2002	Annual	SFY02-00010

Appendix C: Types of Review

The Committee, through its Chair, determines whether the proposal merits exempt review, expedited review, or undergoes full review.

Research Exempt from Full Review

Unless they are covered by some other provision, the following kinds of research are exempt from full review by the Human Research Review Committee:

1. Research conducted in established or commonly accepted education settings, involving commonly used educational practices, such as:

    a) Research on regular and special education instructional strategies; or

    b) Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.

2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; and either:

    a) The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or

    b) The research deals with sensitive aspects of the participants' own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

    a) The observations recorded about the individual, if they become known outside the research, could reasonably place the human participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation; or

    b) The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if the sources are publicly available, or if the information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: Based on the Federal definition of "existing data", research conducted on biological or pathological specimens obtained prospectively and/or taken strictly for research purposes or from future discarded clinical samples DOES NOT qualifies for exempt review.

Expedited Review

The Committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if

1. another agency or organization human research review committee has reviewed and approved the project;

2. the review involves only minor changes in previously approved research and the changes occur during the approved project period; or

3. research activities involve no more than minimal risk and in which the only involvement of human participants will be one or more of the categories referred to in 34 CFR 97.110 as follows:

    a) Clinical studies of drugs or medical devices for which an investigational new drug application or investigational devise exemption application is not required.

    b) Collection of blood samples that meet NIH guidelines; Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

    c) Collection of biological specimens for research purposes by noninvasive means.

    d) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant

amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e) Research involving materials that have been collected solely for nonresearch purposes.

f) Collection of data from voice, video, digital, or image recording made for research purposes;

g) Research on individual or group characteristics that is not exempt;

h) Continuing review of research previously approved;

i) Continuing review of research that does not meet the preceding requirements but which had been reviewed by and research Committee that deems that no greater than minimal risk is involved and no additional risks have been identified.

For the expedited review, the Committee chair and one or more experienced reviewers designated by the chair from among members of the Committee may carry out the review. The reviewers may exercise all of the authorities of the Committee except that the reviewers may not disapprove the research. If the expedited review leads to be for disapproval, the proposals would be sent to the full Committee for review.

All Committee members will receive printed notification of the actions of an expedited review.

Full Review

A full review shall include consideration of the following criteria for approval:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;

2. The degree of the risk, and if the research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the participants are adequately protected;

4. Whether the risks to the participants are outweighed by the potential benefits to them;

5. Whether the voluntary informed consent is to be obtained by methods that adequately and appropriately fulfill the requirements of these regulations and whether the written consent

form is adequate and appropriate in both content and language for the particular research and for the particular participants of the research;

6. Whether the research investigators proposing to supervise or conduct the particular human research are appropriately competent and qualified;

7. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness;

8. Whether appropriate studies in nonhuman systems if applicable have been conducted prior to the involvement of human participants; and

9. Whether the research conforms with other requirements to be developed.

Appendix D: Continuing Review Applications

Study Title	Periodic Review Results	Date of Initial approval	DRS Human Research Control Number
Improving Community-Based Follow-up Services to Address Long-term Health Maintenance Needs for Persons with Spinal Cord Injury Residing in Southwest Virginia.	Investigator used a consent form that had not been reviewed by the Committee. The investigator was sent a written reminder that the Committee must review and approve all proposed changes to previously approved research prior to implementation. The study was approved with the provision that a survey instrument that was developed as part of the research protocol be forwarded for the Committee's review and approval.	5/22/2001	00007
Clean Techniques of Bladder Management: Comparison of Cleaning Methods.	The site visit, conducted on June 25, 2002, identified significant deviations from the approved research protocol and the study was suspended pending receipt of appropriate documentation of the revised protocol and informed consent form and upon the Committee's review and approval.	5/22/2001	00008